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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,026	12/21/2001	Joseph J. Florio	99P1043US01	2420

7590 06/23/2003
PACESETTER, INC.
15900 Valley View Court
Sylmar, CA 91392-9221

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,026

Applicant(s)

FLORIO ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.5. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 13 and 14, "the sinus rate" and "the selected pacing rate" lack antecedent basis. It appears the Applicant may have intended to have claims 13 and 14 depend on claim 12 rather than claim 11. The rejection is written based on this assumption.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-6, 10, 12, 15-23, 27, and 29-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Begemann et al. (US 5978709).

As to claims 1, 3, 17, 18, 20, 29, 30, 32 and 36, the instant device/ method of pacing is disclosed by the special pacing treatment feature, the AFP feature of Pace Conditioning, wherein

the sensed intrinsic beats are one or more, read as two, that are detected, whereupon the higher conditioning pacing repeats (figure 1; col. 2 @ 49 – col. 3 @ 2; col. 8 @ 50-54).

As to claims 2, 4, 6, 10, 19, 21, 23, 27, 31, 33, 37, 38 and 39, the predetermined period is 10 cycles when the increase pace rate is 20 ppm and the increase is limited to 2 ppm/ cycle (col. 8 @ 20-32).

As to claims 5, 22 and 34, when the lower rate limit is reached a pace is provided and the conditioning pacing repeats (col. 6 @ 27-30).

As to claims 12 and 15, the underlying intrinsic rate is the atrial rate or the sinus rate (col. 5 @ 3-5).

As to claim 16, the selected pacing rate is reset to be the updated atrial rate (col. 7 @ 24-50).

As to claims 35 and 40, the predefined period is a predefined period of time (col. 9 @ 11-14).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point

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out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7-9, 11, 24-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begemann et al. (US 5978709) in view of Lu et al. (US 5951593). As discussed in paragraph 3 of this action, Begemann et al. teach the instant device/ methods of pacing.

As to claim 7, 8, 24, and 25, the special pacing treatment feature, the PAC suppression routine, decreases the overdrive pacing rate according to programmed criteria (col. 3 @ 3-14; col. 6 @ 32-65).

As to claims 9 and 26, the second predetermined period is stabilized for a period e.g. 400-1000 beats or 200 to 500 cycles. Absent any teachings of criticality or unexpected result, merely changing the length of the second predetermined period to about 8 to about 40 cycles is viewed as an obvious design choice (col. 6 @ 46-48).

As to claims 11 and 28, the rate is decreased 1-3 ppm per 24-40 beats, read as about 1 to about 5 paces per minute (col. 9 @ 15-17).

Begemann et al. disclose the claimed invention except for the decrement beginning if two intrinsic heart beats are not detected within the second predefined period.

Lu et al. teach cardiac rhythm monitoring using a counter to determine atrial sense signals for the purpose of controlling the pacing algorithm. When, for example, 3 of 8 beats, read of 2 of 8 beats are detected, an output is generated to control the pacing algorithm to prevent the onset of arrhythmias. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the counting to two intrinsic beats to inhibit decrementing

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of the pacing rate in the Begemann et al. system in order to have a proven means to monitor the pacing rhythm and to modify the algorithm accordingly, in this case not reducing the pacing rate, such that the onset of arrhythmias is prevented (col. 1 @ 6-12; col. 6 @ 50-63).

6. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begemann et al. (US 5978709) in view of Elmvist (US 5253644). As discussed in paragraph 3 of this action, Begemann et al. disclose the claimed invention of determining the pacing rate by suspending the pacing (figure 1 – 31, 32; col. 4 @ 50- col 5 @ 13) except for determining the sinus rate based on three consecutive sinus P-waves.

Elmvist teaches rhythm detection using at least two consecutive P-waves, read as three consecutive P-waves, for the purpose of accurately determining cardiac rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used three consecutive P-waves to calculate the sinus rate in the Begemann et al. system in order to use a proven method of rhythm determination and avoid inaccurate evaluation of the cardiac rhythm resulting in delayed treatment of the arrhythmia (abstract; col. 2 @ 26-29).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

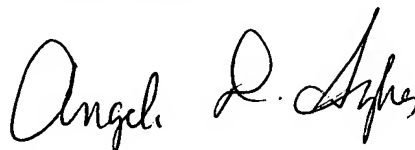
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

6/15/03



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